

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Richard G. Langlois et al

Serial No.: 10/643,797

Filed: 08/19/2003

TITLE: SYSTEM FOR
AUTONOMOUS
MONITORING OF
BIOAGENTS

Examiner: Nelson C. Yang

Art Unit: 1641

Attorney Docket No.: IL-11052

Honorable Commissioner for Patents
Alexandria, VA 22313-1450

Attention: Board of Patent Appeals and Interferences

Dear Sir:

APPELLANT'S REPLY BRIEF (37 C.F.R. § 1.192)

This Reply Brief is submitted in response to the "Examiner's Answer" mailed February 23, 2009. One copy of the Reply Brief is being transmitted.

STATUS OF CLAIMS

The application as originally filed contained claims 1-50. The claims on appeal are claims 1-5, 12, 15-16, 19, 27, 29, and 31-40. The status of all the claims in the proceeding is: Claims 1-5, 12, 15-16, 19, 27, 29, and 31-40 are rejected. Claims 6-11, 13-14, 17-18, 20-26, 28, and 30 are withdrawn. Claims 4-9, 14, 15, 17, and 18 are cancelled.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The Final Rejection mailed September 18, 2008 stated four (4) grounds of rejection. The four grounds of rejection are summarized as follows:

Grounds of Rejection #1 – Claims 1-5, 12, 15, 16, 27, 32, 33, and 35-40 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Irving in view of Casey.

Grounds of Rejection #2 – Claim 19 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Irving in view of Casey and further in view of Colston.

Grounds of Rejection #3 – Claim 29 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Irving in view of Casey and further in view of Fisher.

Grounds of Rejection #4 – Claims 31 and 34 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Irving in view of Casey and further in view of Miles.

REPLY TO EXAMINER'S ANSWER REGARDING GROUNDS #1

(Claims 1-5, 12, 15, 16, 27, 32, 33, & 35-40 rejected under 35 U.S.C. § 103(a) as unpatentable over Irving in view of Casey)

Examiner's Answer Does Not Meet Criterion 1

Appellants point out that elements of Appellants' claims are missing from the Irving reference. In addition to the claim elements the Examiner's Answer admits are missing from the Irving reference, the Irving reference does not show Appellants' following claim elements”

Claim 1

“a collector for gathering said air being monitored, said collector separating selected potential bioagent particles from said air.”

Claim 1

“a detector for detecting said bioagents in said sample, said detector operatively connected to said wetted wall sample preparer wherein said detector utilizes said optically encoded microbeads.”

Claim 5

“wherein said collector is an aerosol collector that collects air and includes means for separating said air into a bypass air flow that does not contain said potential bioagent particles of a predetermined particle size range and a product air flow that contains said potential bioagent particles of a predetermined particle size range.”

Claim 12

“means for lysis of said spores.”

Claim 15

“a sequential injection analysis system.”

Claim 32

“a multiplex PCR detector.”

Claim 36

“a real time PCR detector.”

Claim 37

“means for performing PCR amplification.”

Claim 38

“means for injecting/aspirating a sample, means for adding PCR reagent, means for mixing sample and reagent, means for transport to PCR reactor, means for performing PCR amplification, means for transport of amplified sample from PCR reactor, and means for detection of PCR amplicon.”

Claim 39

“includes means for injecting/aspirating a sample, means for adding PCR reagent, means for mixing sample and reagent, means for transport to PCR reactor, means for performing PCR amplification, means for transport of amplified sample from PCR reactor, means for detection of PCR amplicon, and means for decontamination and conditioning of all exposed conduits.”

Claim 40

“optically encoded microbeads and bead suspension/mixer means for suspending said microbeads for a predetermined time period.”

Since the identified claim elements are missing from the Irving reference and the Casey reference does not provide the missing claim

elements, the Examiner's Answer and the Final Rejection do not meet Criterion 1 that the prior art references must teach or suggest all the claim limitations. Accordingly the rejection in Grounds of Rejection #1 should be reversed.

Examiner's Answer Does Not Meet Criterion 2

Since there are many claim elements missing from the Irving reference and the Casey reference does not provide the missing claim elements, the Examiner's Answer and the Final Rejection do not meet Criterion 2 that must be a reasonable expectation of success with the proposed combination.

Accordingly the rejection in Grounds of Rejection #1 should be reversed.

Examiner's Answer Does Not Meet Criterion 3

The Examiner's Answer contains the following statements on page 4, second paragraph:

"Therefore, it would have been obvious to one of ordinary skill art at the time of the invention to for the detector integrated to the particle separation assembly of Irving et al to comprise a flow cytometer and a unit for adding optically encoded microspheres comprising two fluorescent dyes incorporated in different ratios of red and orange fluorescence, as suggested by Casey et al, in order allow for a greater number of labels, which would allow for multiplexed assays that would allow for a greater number of analytes to be detected."

Appellants respectfully traverse these statements. The statements do not provide reasons why the Casey reference would be combined with the Irving reference. Criterion 3 requires that the Examiner provide reasons for combining the references to produce the proposed combination. Since the Examiner's Answer and the Final Rejection do not meet Criterion 3, the rejection in Grounds of Rejection #1 should be reversed.

REPLY TO EXAMINER'S ANSWER REGARDING GROUNDS #2

(Claim 19 rejected under 35 U.S.C. § 103(a) as unpatentable over Irving in view of Casey and further in view of Colston)

Examiner's Answer Does Not Meet Criterion 1

Appellants point out that elements of Appellants' claim 19 are missing from the Irving reference. The Irving reference does not show Appellants' following claim elements"

Parent Claim 1

"a collector for gathering said air being monitored, said collector separating selected potential bioagent particles from said air."

Parent Claim 1

"a detector for detecting said bioagents in said sample, said detector operatively connected to said wetted wall sample preparer wherein said detector utilizes said optically encoded microbeads."

Claim 19

"The apparatus of claim 1 wherein said wetted wall sample preparer includes a super serpentine reactor."

Since the identified claim elements are missing from the Irving reference and the Casey and Colston references do not provide the missing claim elements, the Examiner's Answer and the Final Rejection do not meet Criterion 1 that the prior art references must teach or suggest all the claim limitations. Accordingly the rejection in Grounds of Rejection #2 should be reversed.

Examiner's Answer Does Not Meet Criterion 2

Since there are many claim elements missing from the Irving reference and the Casey and Colston references do not provide the missing claim elements, the Examiner's Answer and the Final Rejection do not meet Criterion 2 that must be a reasonable expectation of success with the proposed combination. Accordingly the rejection in Grounds of Rejection #2 should be reversed.

Examiner's Answer Does Not Meet Criterion 3

The Examiner's Answer contains the following statements on page 7, third paragraph:

"Colston, Jr. et al, however, teach that mixers such as super serpentine reactors may be used to combine the sample and the PCR reagents (para. 0043). Therefore, one of ordinary skill in the art at the time of the invention, when presented with these two references, would have found it obvious to utilize the super serpentine reactor of Colston, Jr. et al to perform the mixing of the reagents and PCR sample during the PCR preparation stage in the invention of Irving et al and Casey et al, in order to ensure a proper mixing of the PCR sample with the reagents so that accurate PCR amplification and analysis may be performed."

Appellants respectfully traverse these statements. The statements do not provide reasons why the Casey reference and the Colston reference would be combined with the Irving reference. Criterion 3 requires that the Examiner provide reasons for combining the references to produce the proposed combination. Since the Examiner's Answer and the Final Rejection do not meet Criterion 3, the rejection in Grounds of Rejection #2 should be reversed.

REPLY TO EXAMINER'S ANSWER REGARDING GROUNDS #3

(Claim 29 rejected under 35 U.S.C. § 103(a) as unpatentable over Irving in view of Casey and further in view of Fisher)

Examiner's Answer Does Not Meet Criterion 1

Appellants point out that elements of Appellants' claim 29 are missing from the Irving reference. The Irving reference does not show Appellants' following claim elements"

Parent Claim 1

"a collector for gathering said air being monitored, said collector separating selected potential bioagent particles from said air."

Parent Claim 1

“a detector for detecting said bioagents in said sample, said detector operatively connected to said wetted wall sample preparer wherein said detector utilizes said optically encoded microbeads.”

Claim 29

“The apparatus of claim 1 wherein said flow cytometer for analyzing said optically encoded microbeads with said laser unit includes a red laser that classifies said microbeads and a green laser that quantifies said microbeads.”

Since the identified claim elements are missing from the Irving reference and the Casey and Fisher references do not provide the missing claim elements, the Examiner’s Answer and the Final Rejection do not meet Criterion 1 that the prior art references must teach or suggest all the claim limitations. Accordingly the rejection in Grounds of Rejection #3 should be reversed.

Examiner’s Answer Does Not Meet Criterion 2

Since there are many claim elements missing from the Irving reference and the Casey and Fisher references do not provide the missing claim elements, the Examiner’s Answer and the Final Rejection do not meet Criterion 2 that must be a reasonable expectation of success with the proposed combination. Accordingly the rejection in Grounds of Rejection #3 should be reversed.

Examiner’s Answer Does Not Meet Criterion 3

The Examiner’s Answer contains the following statements in the paragraph that bridges pages 7 and 8:

“Fisher et al, however, teaches a FACS machine for use in flow cytometry analysis (column 4, lines 47-55, 59-68), wherein multiple different lasers may each be used such that different measurements may be determined simultaneously from an individual particle (column 5, lines 48-65), wherein the lasers may be used to excite orange, red, green, and blue dyes (column 7, lines 65-column 8, lines 1-11), which would involve red and green lasers.”

Appellants respectfully traverse these statements. The statements do not provide reasons why the Casey reference and the Fisher reference would be combined with the Irving reference. Criterion 3 requires that the Examiner provide reasons for combining the references to produce the proposed combination. Since the Examiner's Answer and the Final Rejection do not meet Criterion 3, the rejection in Grounds of Rejection #3 should be reversed.

REPLY TO EXAMINER'S ANSWER REGARDING GROUNDS #4

(Claims 31 and 34 rejected under 35 U.S.C. § 103(a) as unpatentable over Irving in view of Casey and further in view of Miles)

Examiner's Answer Does Not Meet Criterion 1

Appellants point out that elements of Appellants' claims 31 and 34 are missing from the Irving reference. The Irving reference does not show Appellants' following claim elements"

Parent Claim 1

"a collector for gathering said air being monitored, said collector separating selected potential bioagent particles from said air."

Parent Claim 1

"a detector for detecting said bioagents in said sample, said detector operatively connected to said wetted wall sample preparer wherein said detector utilizes said optically encoded microbeads."

Claim 31

"The apparatus of claim 1 wherein said detector includes a liquid-array based multiplex immunoassay detector."

Parent Claim 33

"The apparatus of claim 1 including confirmation means for confirming said bioagents in said sample."

Claim 34

"The apparatus of claim 33 wherein said confirmation means is a multiplex immunoassay detector."

Since the identified claim elements are missing from the Irving reference and the Casey and Miles references do not provide the missing claim elements, the Examiner's Answer and the Final Rejection do not meet Criterion 1 that the prior art references must teach or suggest all the claim limitations. Accordingly the rejection in Grounds of Rejection #4 should be reversed.

Examiner's Answer Does Not Meet Criterion 2

Since there are many claim elements missing from the Irving reference and the Casey and Miles references do not provide the missing claim elements, the Examiner's Answer and the Final Rejection do not meet Criterion 2 that must be a reasonable expectation of success with the proposed combination. Accordingly the rejection in Grounds of Rejection #4 should be reversed.

Examiner's Answer Does Not Meet Criterion 3

The Examiner's Answer contains the following statements in the last paragraph on page 9:

"Miles et al, however, teach both immunoassay and PCR detectors (see 46, 77 of the figure). More specifically, Miles et al teach a flow cytometer for analysis of the antibody coated beads (column 4, lines 26-28), which would also be capable of functioning as a liquid array based multiplex immunoassay or PCR detector for analyzing infection agents and spores (column 2, lines 50-65), and which would be capable of analyzing optically encoded microbeads, such as those of Casey et al. (column 3, lines 25-41). Miles et al also teach the use of Taqman assays (column 4, lines 60-65) which are quantitative PCR assays and which would require a PCR detector, and that the fluorescent signal is detected in real-time (column 4, lines 64-65)."

Appellants respectfully traverse these statements. The statements do not provide reasons why the Casey reference and the Miles reference would be combined with the Irving reference.

Also, the Examiner's Answer contains the following statements in the first paragraph on page 10:

"Therefore, Miles et al show that multiplexed immunoassay detectors and multiplexed PCR detectors are equivalent structures known in the art. Therefore, because these two types of detectors were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute a multiplexed immunoassay detector for a PCR detector."

The fact that two detectors are shown in the Miles reference does not provide reasons why the Irving reference and the Casey reference would be combined with the Miles reference.

Criterion 3 requires that the Examiner provide reasons for combining the references to produce the proposed combination. Since the Examiner's Answer and the Final Rejection do not meet Criterion 3, the rejection in Grounds of Rejection #4 should be reversed.

Summary

Appellants' claims are unobvious over the references cited in the Final Rejection and the Examiner's Answer. The rejection of Appellants' claims on appeal should be reversed. It is respectfully requested that Appellants' claims 1-5, 12, 15-16, 19, 27, 29, and 31-40 on appeal be allowed.

Respectfully submitted,

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